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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,272	08/20/2004	Stephen Kerr	127272.00111	5520
21269	7590	09/11/2006	EXAMINER	
PEPPER HAMILTON LLP ONE MELLON CENTER, 50TH FLOOR 500 GRANT STREET PITTSBURGH, PA 15219			POUS, NATALIE R	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/505,272	Applicant(s) KERR, STEPHEN	
	Examiner Natalie Pous	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5 and 7-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/22/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments/Remarks

Regarding the 112 rejection

Upon receipt of amended claims and the addition of claim 15, the previous 112 rejection with respect to claim 9 is withdrawn.

Regarding art rejections

Applicant's arguments with respect to claims 1-14 have been considered but are moot in view of the new ground(s) of rejection.

Regarding the Double Patenting Rejection

Upon receipt of the terminal disclaimer, the previous double patenting rejection is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 7-9 and 14-16 rejected under 35 U.S.C. 102(b) as being anticipated by Gordon (US 5741277).

Regarding Claim 1, Gordon teaches a device for fashioning a closure of a puncture site in a tissue (2) comprising: a cannula member (32) having proximal and distal ends and a lumen; a connecting rod (38) disposed axially within said cannula,

said connecting rod having a proximal end oriented towards said proximal end of said cannula and a distal end oriented toward said distal end of said cannula, said connecting rod having an actuating mechanism (124) operative to selectively cause said connecting rod to advance distally or retract proximally within said cannula (fig. 2 to fig. 3) a needle/suture complex (42) mounted upon said distal end of said connecting rod (38), said needle/suture complex comprising at least one pair of needles (6) having a suture extending there between (4), said needles being operative to assume an operative configuration wherein said needles extend in opposed directions from the distal end of said cannula such that each respective needle extends from a periphery of a puncture site (fig. 1b), said needle/suture complex further comprising two or more needle holder arms (58a,b) connected to the distal end (54) of said connecting rod, said connecting rod operative to pivot the needle holder arms between a first operative configuration wherein said needle holder arms extend in opposed directions from the distal end of said cannula (fig. 1f), and a second operative configuration wherein said needle holder arms are biased inwardly relative to said first operative configuration and into the lumen of said cannula (fig. 4a) and a needle trap mechanism (16) disposed within the lumen of said cannula and operative to lockingly engage said needles (6) of said needle/suture complex after said needle holder arms assume the second operative configuration; and wherein said needle trap mechanism is operative to draw said needles into the lumen of said cannula (fig. 1g) such that the device may be withdrawn from the puncture site with the suture extending between the needles, forming a closure of said puncture site (fig. 1h).

Regarding Claim 2, Gordon teaches the device of claim 1, wherein said needles (6) are further operative to assume one or both of the following additional configurations: a folded configuration wherein said needles are operative to extend through the lumen of said cannula, and a retracted wherein said needles are biased inwardly toward the lumen of said cannula (fig. 1d).

Regarding Claim 3, Gordon teaches the device of claim 2 wherein the distal end of said cannula (32) is positionable through a puncture site in a tissue (14).

Regarding Claim 5, Gordon teaches the device of claim 4 wherein each respective one of said pair of needles is operative to disengage from said needle holder arms after each needle holder arm transitions from its first operative configuration to its second operative configuration (fig. 1d to fig. 1e).

Regarding Claim 7, Gordon teaches the device of claim 1 wherein each respective one of said pair of needle holder arms are biased to extend i across said puncture site as said needle holder arms assume said first operative configuration (fig. 1b).

Regarding Claim 8, Gordon teaches the device of claim 1 further comprising a handle (34a) formed upon said cannula.

Regarding Claim 9, Gordon teaches the device of claim 15 wherein said handle (34a) and said trigger (124) are positioned relative one another to enable the handle to be grasped and the trigger to be manipulated by a single hand of a user.

Regarding Claim 14, Gordon teaches the device of claim 1 wherein said actuating mechanism is a trigger (124).

Regarding Claim 15, Gordon teaches the device of claim 8 further comprising a trigger (124) formed on the proximal end of said connecting rod and operative to selectively cause said connecting rod to advance distally or retract proximally within said cannula.

Regarding Claim 16, Gordon teaches a device for fashioning a closure of a puncture site in a tissue (2) comprising: a cannula member (32) having proximal and distal ends and a lumen; a connecting rod (38) disposed axially within said cannula, said connecting rod having a proximal end oriented towards said proximal end of said cannula and a distal end oriented toward said distal end of said cannula, said connecting rod having an actuating mechanism (124) operative to selectively cause said connecting rod to advance distally or retract proximally within said cannula (fig. 2 to fig. 3) ; two or more needle holder arms (58a,b) connected to the distal end (54) of said connecting rod, said connecting rod operative to pivot the needle holder arms between a first operative configuration wherein said needle holder arms extend in opposed directions from the distal end of said cannula (fig. 1f), and a second operative configuration wherein said needle holder arms are biased inwardly relative to said first operative configuration and into the lumen of said cannula (fig. 4a); at least one pair of needles (6) having a suture extending therebetween; each of said needles mounted upon, respectively, each of said needle holder arms (58a,b); and a needle trap mechanism (16) disposed within the lumen of said cannula and operative to lockingly engage said needles (6) of said needle/suture complex after said needle holder arms assume the second operative configuration; and wherein said needle trap mechanism is

operative to draw said needles into the lumen of said cannula (fig. 1g) such that the device may be withdrawn from the puncture site with the suture extending between the needles, forming a closure of said puncture site (fig. 1h).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein et al. (US 5860991) in view of Bradley et al. (US 5374275).

Klein teaches a device for fashioning a closure of a puncture site in a tissue (10) comprising the following:

- a cannula member (s) having proximal and distal ends and a lumen
- a connecting rod (14) disposed axially within said cannula
- said connecting rod having a proximal end oriented towards said proximal end of said cannula and a distal end oriented toward said distal end of said cannula
- said connecting rod having an actuating mechanism (16) operative to selectively cause said connecting rod to advance distally or retract proximally within said cannula (fig. 10 to fig. 11)
- a needle/suture complex (18) mounted upon said distal end of said connecting rod

- said needle/suture complex comprising at least one pair of needles (20) having a suture extending therebetween (30)
- said needles being operative to assume an operative configuration wherein said needles extend in opposed directions from the distal end of said cannula such that each respective needle extends from a periphery of a puncture site (BV)
- a needle trap mechanism (32) disposed within the lumen of said cannula and operative to lockingly engage said needles (20) of said needle/suture complex when said needles assume the operative configuration
- and wherein said needle trap mechanism is operative to draw said needles into the lumen of said cannula (fig. 11) such that the device may be withdrawn from the puncture site with the suture extending between the needles forming a closure of said puncture site (fig. 12).
- wherein said needles (20) are further operative to assume one or both of the following additional configurations: a folded configuration wherein said needles are operative to extend through the lumen of said cannula, and a retracted wherein said needles are biased inwardly toward the lumen of said cannula (fig. 11).
- wherein said needle trap mechanism comprises a cylindrical sleeve (32) axially mounted about said connecting rod (14) within said cannula (s), said needle trap mechanism having a proximal end with a lever (16) formed thereon, and a distal end (fig. 9) having a needle catch (32) formed therein, said needle catch being

operative to lockingly engage with said needles of said needle/suture complex after said needle assumes said second operative configuration.

- wherein said lever formed upon said needle trap mechanism is operative to cause said needle trap mechanism to extend distally and retract proximally within the said cannula (fig. 10 to fig. 11).
- wherein said needle trap mechanism, when lockingly engaged with said needle tips of said needles, disengages said needles from said needle holder and then captures said needles within said cannula when said needle trap mechanism retracts proximally within said cannula (fig. 10 to fig. 11).

Klein fails to teach said needle/suture complex further comprising two or more needle holder arms connected to the distal end of said connecting rod, said connecting rod operative to pivot the needle holder arms between a first operative configuration and wherein said needle holder arms extend in opposed directions from the distal end of said cannula and a second operative configuration wherein said needle holder arms are biased inwardly relatively to said first operative configuration and into the lumen of the cannula.

Bradley teaches a device for closing a puncture comprising two or more needle holder arms (20) connected to the distal end of said connecting rod (24), said connecting rod operative to pivot the needle holder arms between a first operative configuration and wherein said needle holder arms extend in opposed directions from the distal end of said cannula (fig. 7) and a second operative configuration wherein said needle holder arms are biased inwardly relatively to said first operative configuration

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and into the lumen of the cannula (fig. 6) in order to safely store the needles within the cannula when not in use. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Klein with the pivoting arms as taught by Bradley in order to safely store the needles within the cannula when not in use.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon as a matter of design choice. Gordon teaches all aspects of preceding dependent claim 1, but fails to disclose wherein a tapered mount is formed upon said distal end of said connecting rod and holding said needle/suture complex, said tapered mount having a generally hourglass shape. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the distal end of the connecting rod of Gordon with an hourglass shaped tapered mount since it has been held that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art. In re *Karlson*, 136 USPQ 184.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
8/30/06


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

7/5/06